K06180 /

BIOMET

510(k) Summary

AUG - 7 2006

Preparation Date: June 23, 2006

Applicant/Sponsor: Arthrotek, Inc.

Contact Person: Susan Alexander

Proprietary Name: 2.8 and 3.5mm LactoScrew® Suture Anchors

Common Name: Resorbable suture anchor

Classification Name: Fastener, Fixation, Biodegradable, Soft Tissue (21 CFR §888.3030)

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:

- Resorbable Interference Screw K041274 Biomet, Inc.
- LactoSorb® Screw Anchors K003273 Biomet, Inc.

Device Description: The 2.8 and 3.5mm LactoScrew® Suture Anchors, which are comprised of LactoSorb® resorbable copolymer (85% PLLA/15% PGA), are molded suture anchors used to reattach soft tissue to bone. All 2.8 and 3.5mm LactoScrew® Suture Anchors are pre-loaded with either one or two sutures.

Intended Use: Indications for the 2.8 and 3.5 mm LactoScrew® Suture Anchors include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow and knee. Specific indications are as follows:

Shoulder: Bankart repair, SLAP lesion repair, acromio-clavicular separation, rotator cuff repair, capsule repair or capsulolabral reconstruction, biceps tendodesis, deltoid repair.
Wrist/Hand: Scapholunate ligament reconstruction, ulnar/radial collateral ligament reconstruction.
Ankle/Foot: Lateral stabilization, medial stabilization, Achilles tendon repair/reconstruction, hallux valgus reconstruction, mid- and forefoot reconstruction.
Elbow: Tennis elbow repair, ulnar or radial collateral ligament reconstruction, biceps tendon reconstruction.
Knee: Medial collateral ligament repair, lateral collateral ligament repair, posterior oblique ligament repair, joint capsule closure, iliotibial band tendodesis, and patellar ligament/tendon repair.

Summary of Technologies: The technological characteristics (material, design, sizing, indications) of the 2.8 and 3.5mm LactoScrew® Suture Anchors are similar or identical to the predicate devices.

Non-Clinical Testing: Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the devices were functional within their intended use.

Clinical Testing: None provided as a basis for substantial equivalence.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 7 2006

Athrotek, Inc.
% Biomet Manufacturing Corp.
Ms. Susan Alexander
Regulatory Specialist
P.O. Box 587
Warsaw, Indiana 46581-0587

Re: K061801
Trade/Device Name: 2.8 and 3.5mm LactoScrew® Suture Anchors
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: JDR, HWC
Dated: June 23, 2006
Received: June 26, 2006

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

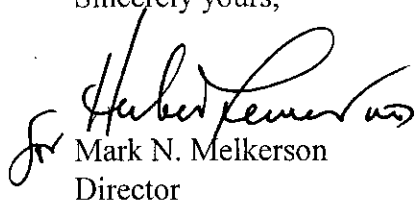
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061801

Device Name: 2.8 & 3.5mm LactoScrew® Suture Anchors

Indications For Use:

Indications for the 2.8 and 3.5mm LactoScrew® Suture Anchors include use in soft tissue reattachment procedures in the shoulder, wrist/hand, ankle/foot, elbow and knee. Specific indications are as follows:

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Prescription Use ___X___ AND/OR Over-The-Counter Use __NO__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K061801